Vaccines and immunity

**OC - (8546) - SAFETY AND IMMUNOGENICITY OF THE MALARIA VACCINE CANDIDATE BK-SE36 IN YOUNG CHILDREN LIVING IN BURKINA FASO**

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**Background**

The malaria blood stage vaccine candidate SE-36 is based on the serine repeat antigen of *Plasmodium falciparum*. Epidemiological studies have shown that antibodies against SE36 correlates with lower parasitemia in Solomon Island residents. In a phase Ib trial conducted in Uganda, the BK-SE36 vaccine, SE36 formulated with aluminium hydroxide gel, was found safe and immunogenic. Interestingly, highest level of IgG anti-SE36 protein associated with protection against severe malaria were found in the youngest Ugandan trial participants.

**Objectives**

To assess the safety and immunogenicity of the BK-SE36 vaccine in a randomised controlled double blind age deescalating phase Ib clinical trial in younger (≤ 5 years) malaria exposed children living in Burkina Faso.

**Methods**

Healthy participants (108) were included in two age cohorts, one consisting of 54 children aged 25-60 months and the other of 54 children aged 12-24 months. Trial participants received 3 intramuscular or subcutaneous injections of the BK-SE36 vaccine at Day0, Week 4 and 26. Participants allocated to the control group received the control Synflorix® vaccine via intramuscular route at Day 0 and Week 26 and saline at Week 4. The participants were followed during one year. Immune responses were evaluated by ELISA, ELISpot and parasite carriage by microscopy and PCR.

**Results**

Preliminary data from an interim analysis data collected one month after the last immunisation indicated that the vaccine was safe, well tolerated and induced an IgG anti-SE36 response in these younger populations. The trial latest safety, immunogenicity and preliminary efficacy results will be presented.